



Hiossen Inc.

85 Ben Fairless Dr. Fairless Hills, PA 19030

Tel : 1-888-678-0001 / Fax : 1-267-759-7004

www.hiossen.com

JUN 28 2013

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 28, 2012

### 1. Company and Correspondent making the submission:

- Submitter's Name : HIOSSEN Inc.  
 - Address : 85 Ben Fairless Dr.  
 Fairless Hills PA 19030  
 - Telephone No. : 888 678 0001  
 - Contact : Mr. Patrick Lim

### 2. Device :

Trade or (Proprietary) Name : ET SmartFit Abutment  
 Common or usual name : Dental Device  
 Classification Name : Abutment, implant, dental, endosseous  
 21CFR872.3630  
 Class II  
 NHA

### 3. Predicate Device :

K110308, The Prosthetic System, Osstem Implant Co., Ltd.

### 4. Description :

1) The ET SmartFit Abutment is device made of titanium alloy intended for use as an aid in prosthetic restoration. That is customized abutment considering shape of the final prosthesis based on the patient's mouth model using CAD/CAM system during the manufacturing. All manufacturing processes of ET SmartFit abutment such as CAD/CAM manufacturing and milling are conducted in the Hiossen factory

range of diameters	Ø4 mm ~ Ø15mm
possible range of angulations	0° ~ 30°
type of implant-abutment connection ports	Hex (2.1mm, 2.5mm) Non Hex


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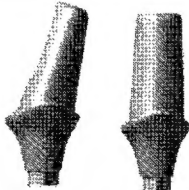
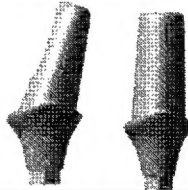
2) The ET SmartFit Abutment is used for cement-retained crowns and bridges using customized abutment considering based on the patient's mouth using CAD/CAM system. Use only the basal screws provided for the Customized Abutment. The surgical procedure for Customized abutment is the same as the surgical procedure for the cement-retained abutments.

3) The ET SmartFit Abutment is the same with other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

4) The ET SmartFit Abutment is substantially equivalent in design, function and intended use to the Prosthetic System (K110308) of Osstem Implant Co., Ltd.

5) The ET SmartFit Abutment is used with ETIII SA Fixture (K101096)

**- Substantial Equivalence Matrix**

	<b>ET SmartFit Abutment</b>	<b>Prosthetic System (Custom Abutment)</b>
<b>Manufacturer</b>	HIOSEN Inc.	Osstem Implant Co., Ltd
<b>510(k) Number</b>	New	K110308
<b>Design</b>		
<b>Intended use</b>	ET SmartFit Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
<b>Material</b>	Titanium Alloy (Ti-6Al-4V)	Titanium Alloy (Ti-6Al-4V)

**5. Indication for use :**

ET SmartFit Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.



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6. Review :

ET SmartFit Abutment has the same material, indication for use, design and technological characteristics as the predicate device.

ET SmartFit Abutment has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable international and US regulations.

7. Summary of nonclinical testing

The Fatigue testing for ET SmartFit Abutment was conducted according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" and ISO 14801 Dentistry - Fatigue test for endosseous dental implants with the worst case scenario. The results are in compliance with it and were similar to previously cleared predicate devices."

8. Summary of clinical testing

No clinical studies are submitted because the ET SmartFit Abutment has the same materials, manufacturing process, chemical composition, indication for use and body contact as Prosthetic System (K110308). Additionally, we certify that ET SmartFit Abutment is not processed that length of post is under 4mm and angulations is under 30°

9. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification HIOSSEN Inc. concludes that the ET SmartFit Abutment is substantially equivalent to the predicate devices as described herein



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

June 28, 2013

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Mr. Patrick Lim  
Manager  
HIOSEN, Incorporated  
85 Ben Fairless Drive  
FAIRLESS HILLS PA 19030

Re: K123627

Trade/Device Name: ET SMARTFit Abutment  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: II  
Product Code: NHA  
Dated: May 29, 2013  
Received: June 5, 2013

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Kwame O. Ulmer -S**

Kwame Ulmer, M.S.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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510(k) Number K K123627

Device Name : ET SMARTfit Abutment

Indication for use : ET SMARTfit Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

Prescription Use X  
(Per 21CFR801 Subpart D)

OR Over-The-Counter Use \_\_\_\_\_  
(Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S  
2013.06.28 09:27:33 -04'00'

for Susan Runner, DDS, MA

(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K123627